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Paper 17
Entered: 14 April 2009

4 UNITED STATES PATENT AND TRADEMARK OFFICE
5 BOARD OF PATENT APPEALS AND INTERFERENCES

8 Patent Interference 105,685 McK
9 Technology Center 1600

12 **SEPRACOR, INC.**

13 (Named inventors: Thomas P. Jerussi, Chrisantha H. Senanayake,
14 and Nandkumar N. Bhongle)

15 Applications 10/720,134, 11/091,518 and 12/011,083,

17 v.

19 **WYETH**

20 (Named inventors: Anthony F. Hadfield, Syed M. Shah,
21 James A. Provost, Aeri Park, Rex A. Shipplett,
22 Brenton W. Russell, and Beat T. Weber),
23 Patents 6,673,838 B2 and 7,291,347 B2.

26 Before: Fred E. McKelvey, *Senior Administrative Patent Judge*.

28 **REDECLARATION and CONSOLIDATION ORDER**

29 **A. Conference calls**

30 Telephone conference calls were held on 1 April 2009 at approximately

31 8:00 a.m. (0800 hours, Hawaii Standard Time) and 7 April 2009 at approximately

32 8:00 a.m. (0800 hours, Hawaii Standard Time), involving:

- 33 1. Steven P. O'Connor, Esq., and Carlos M. Téllez, Esq., counsel for
34 Wyeth,

- 1 2. Thomas E. Friebel, Esq. and Jennifer Chheda, Esq., counsel for
2 Sepracor, Inc., and
3 3. Fred E. McKelvey, Senior Administrative Patent Judge.

4 **B. Consolidation of interferences**

5 Tablet Interference 105,671 and Compound Interference 105,685 and
6 Carrier Interference 105,689 are consolidated into a single proceeding.
7 All papers are to be filed in Compound Interference 105,685.
8 No further papers are to be filed in Tablet Interference 105,671 or Carrier
9 Interference 105,689.

10 Interference 105,671 and Interference 105,689 will be administratively
11 terminated without entry of judgment. Administrative termination of Interference
12 105,671 and Interference 105,689 will not form the basis for any estoppel under
13 37 C.F.R. § 41.127(a).

14 In all future papers, the heading used in this order shall be used.

15 At this time, the heading does not identify a "senior" or a "junior" party.

16 Pursuant to a suggestion by Sepracor, both Michael W. Winkely and Karen
17 W. Sutherland are not identified as named inventors in the heading.

18 A party filing a motion has the burden of proof. 37 C.F.R. § 41.121(b).

19 If necessary, after all authorized motions are decided and benefit becomes
20 fixed, one party will be designated as "senior" party and the other designated as
21 "junior" party for action during any priority phase.

22 Papers previously filed in both Interference 105,671 and Interference
23 105,689 are to be considered as though they were filed in this interference without
24 any need for the papers to be re-filed in this interference file.

25 **C. Redeclaration of Interference 105,685**

26 The interference is redeclared as follows.

- 1 1. Count 1 (Paper 1, page 8) is removed from Interference 105,685.

2 2. To minimize confusion, there will be no counts numbered Count 2,

3 Count 3 or Count 4. Those count numbers were used by Sepracor in its motions

4 lists.

5 3. Count 5 is added (to replace Count 1 in compound Interference

6 105,685—the language being essentially the same with bold matter being what has

7 been added) as follows:

Count 5

The compound of claim 1 of Hadfield U.S. Patent 6,673,838 B2

or

the compound of claim 60 of Jerussi application 10/720,134.

12 Hadfield U.S. Patent 6,673,838 B2 claim 1 reads:
13

A compound which is O-desmethyl venlafaxine succinate.

Jerussi application 10/720,134 claim 60 reads:

A compound which is O-desmethylvenlafaxine succinate.

The claims of the parties are:

Hadfield '838: 1-46

Jerussi '134: 60-71

The claims that correspond to Count 5 are:

Hadfield '838: 1-3'

Jerussi '134: 60-62

¹ Pursuant to discussion during the conference call, Hadfield '838 claims 23-30 and 33-34 and Jerussi '134 claims 63-71 previously designated as corresponding to Count 1 in Compound Interference 105,685 are now designated as corresponding to Count 7.

The claims that do not correspond to Count 5 are:

Hadfield '838: 4-46

Jerussi '134: 63-71

With respect to Count 5, the parties are accorded an earlier constructive reduction to practice (*i.e.*, benefit for the purpose of priority) of the following applications:

Hadfield: None

Jerussi: Application 09/527,442,
filed 17 March 2000

11 4. Count 6 is added (to replace Count 1 in Tablet Interference
12 105,671 involving Jerussi application 12/011,083 and Hadfield patent 7,291,347
13 B2—the language of Count 6 is the same as Count 1 of Tablet Interference
14 105,671) as follows:

Count 6

An oral dosage form comprising O-desmethyl venlafaxine succinate, wherein the oral dosage form is a tablet or capsule.

The claims of the parties are:

Jerussi '083: 60-63

Hadfield '347: 1-9

The claims that correspond to Count 6 are:

Jerussi '083: 60-63

Hadfield '347: 1-9

The claims that do not correspond to Count 6 are:

Jerussi '083: None

Hadfield '347: None

With respect to Count 6, the parties are accorded an earlier constructive reduction to practice (*i.e.*, benefit for the purpose of priority) of the following applications:

4 Jerussi: None

5 Hadfield: Application 10/985,292,
6 filed 10 November 2004,
7 now U.S. Patent 7,026,508,
8 issued 11 April 2006

10 Application 10/654,756,
11 filed 04 September 2003

Application 10/073,743,
filed 11 February 2002,
now U.S. Patent 6,673,838,
issued 06 January 2004

17 5. Count 7 is added (to replace Count 1 in Carrier Interference
18 105,689—the language being essentially the same with bold matter being what has
19 been added) as follows:

Count 7

21 The composition of claims 23, 25 or 26 of

Hadfield U.S. Patent 6,673,838 B2

or

24 the composition of claims 1 or 64 of Jerussi application 11/091,518

or

the composition and dosage form claims 63-65 of

Jerussi application 10/720,134.

29 Hadfield claim 23 reads:

30 A pharmaceutical composition comprising O-desmethyl venlafaxine
31 succinate and a pharmaceutically acceptable carrier or excipient.

1 Hadfield claim 25 reads:

2 A pharmaceutical dosage form comprising a therapeutically effective
3 amount of O-desmethyl venlafaxine succinate and a pharmaceutically
4 acceptable carrier or excipient.

5 Hadfield claim 26 reads:

6 An oral dosage form comprising a therapeutically effective amount of
7 O-desmethyl venlafaxine succinate and a pharmaceutically acceptable
8 carrier or excipient.

9 Jerussi claim 1 of application 11/091,518 reads:

10 A pharmaceutical composition which comprises
11 (\pm)-O-desmethylvenlafaxine succinate and a pharmaceutically
12 acceptable carrier or excipient, wherein (\pm)-O-desmethylvenlafaxine
13 is present at an amount of about 50 mg.

14 Jerussi claim 64 of application 11/091,518 reads:

15 A pharmaceutical composition which comprises
16 (\pm)-O-desmethylvenlafaxine succinate and a pharmaceutically
17 acceptable carrier or excipient, wherein (\pm)-O-desmethylvenlafaxine
18 is present at an amount of about 100 mg.

19 Jerussi claim 63 of application 10/720,134 reads:

20 A pharmaceutical composition comprising a therapeutically effective
21 amount of O-desmethylvenlafaxine succinate and a pharmaceutically
22 acceptable carrier or excipient.

23 Jerussi claim 64 of application 10/720,134 reads:

1 A pharmaceutical dosage form comprising a therapeutically effective
2 amount of O-desmethylvenlafaxine succinate and a pharmaceutically
3 acceptable carrier or excipient.

4 Jerussi claim 65 of application 10/720,134 reads:

5
6 An oral dosage form comprising a therapeutically effective amount of
7 O-desmethylvenlafaxine succinate and a pharmaceutically acceptable
8 carrier or excipient.

9
10 The claims of the parties are:

11 Hadfield '838: 1-46

12 Jerussi '518: 1, 12 and 60-69

13 Jerussi '134: 60-71

14 The claims that correspond to Count 7 are:

15 Hadfield '838: 23-34 and 46.²

16 Jerussi '518: 1, 12 and 60-69

17 Jerussi '134: 63-71

18 The claims that do not correspond to Count 7 are:

19 Hadfield '838: 1-22 and 35-45

20 Jerussi '518: None

21 Jerussi '134: 60-62

² Hadfield '838 claims 23-30 and 33-34 and Jerussi '134 claims 63-71 previously designated as corresponding to Count 1 in Compound Interference 105,685 are now designated as corresponding only to Count 7.

1 With respect to Count 7, the parties are accorded an earlier constructive
2 reduction to practice (*i.e.*, benefit for the purpose of priority) of the following
3 applications:

4 Hadfield: None

5
6 Jerussi: Application 10/720,134,
7 filed 25 November 2003

8
9 Application 09/527,442,
10 filed 17 March 2000

11

12 **D. Exhibits**

13 Wyeth is assigned Exhibit Numbers 1001-1999.

14 Sepracor is assigned Exhibits Numbers 2001-2999.

15 To date, the only exhibits filed in the three interferences are Sepracor
16 Exhibits 2001 through 2007 in Tablet Interference 105,671.

17 In the event Sepracor needs to rely on any of those exhibits in this
18 interference, the exhibit should be re-filed in this interference.

19

20 **E. Settlement discussions**

21 As noted earlier, neither party has been designated as "senior" party at this
22 time. For the purpose of Standing Order ¶ 126.1 (Paper 2, pages 40-41) (see also
23 Declaration, Paper 1, page 7), Sepracor will be responsible for initiating settlement
conferences pending a determination of who is senior party.

24

25 **F. Motion numbers**

26 To date, no motions were filed in any of the three interferences.

27 Accordingly, the parties may number motions consistent with the rules and
the STANDING ORDER, subject to Part G of this order.

1 **G. Motions authorized in this consolidated interference**

2 An ORDER AUTHORIZING MOTIONS and SETTING TIMES entered
3 concurrently with this order (1) identifies motions authorized to be filed in this
4 consolidated interference and (2) provides the rationale for authorizing or not
5 authorizing the filing of motions listed by the parties in their respective motions
6 lists in all three interferences.

7 What follows is a re-identification of authorized motions with appropriate
8 motions numbers. The parties should use the motions numbers set out in this
9 order. In some instances, two or more authorized motions are combined into a
10 single motion.

11 **Jerussi Substantive Motion 1:**³ For benefit of earlier filed Jerussi
12 applications:

- 13 (1) 10/720,134 (filed 25 Nov. 2003)
14 (2) 09/527,442 (filed 17 Mar. 2000)
15 (3) provisional application 60/167,906 (filed 30 Nov. 1999) and
16 (4) provisional application 60/127,938 (filed 6 Apr. 1999).

17 **Jerussi Substantive Motion 2:**⁴ seeking to add Counts 8 and 9:

18 Proposed Count 8 (previously identified by Jerussi as proposed Count 2)

19 reads:

20 A method of treating a patient suffering from *depression*
21 comprising providing to a patient in need thereof an effective amount
22 of O-desmethylvenlafaxine succinate.

³ Corresponding to authorized (1) Jerussi 105,671 Substantive Motion 4,
(2) Jerussi 105,671 Substantive Motion 5, (3) Jerussi 105,685 Substantive
Motion 3 and (4) Jerussi 105,689 Substantive Motion 3.

⁴ Corresponding to authorized Jerussi 105,685 Substantive Motion 5.

Proposed Count 9 (previously identified by Jerussi as proposed Count 3):

A method of treating a patient suffering from *anxiety* comprising providing to a patient in need thereof an effective amount of O-desmethylvenlafaxine succinate.

Jerussi Substantive Motion 3:⁵ Seeking to designate as not corresponding

6 to count 7 the subject matter of Jerussi application 11/091,518 claims 1, 12 and
7 60-69.

Jerussi Responsive Motion 4:⁶ Seeking to add proposed Claim 64 to
oved Jerussi application 12/011,083. Proposed claim 64 would read:

10 64. An oral dosage form comprising a therapeutically effective
11 amount of O-desmethylvenlafaxine succinate and a pharmaceutically
12 acceptable carrier or excipient, wherein the dosage form is a tablet or
13 capsule.

⁵ Corresponding to originally authorized Jerussi 105,689 Substantive Motion 1. The originally authorized motion would have sought an order determining that there is no interference-in-fact between (1) the subject matter of Hadfield U.S. Patent 6,673,838 claims 23-24 and (2) the subject matter of Jerussi application 11/091,518 claims 1, 12 and 60-69. During the conference call on 7 April 2009, it was agreed the motion would be a motion to designate the '518 claims as *not* corresponding to Count 7 because Jerussi '134 now has claims designated as corresponding to Count 7.

⁶ Corresponding to authorized Jerussi 105,671 Responsive Motion 3, to be filed in Time Period 2.

1 **Hadfield Substantive Motion 1:**⁷ For benefit of earlier filed Hadfield
2 applications:

- 3 (1) provisional application 60/297,963 (13 Jun. 2001) and
4 (2) provisional application 60/268,214 (12 Feb. 2001).

5 **Hadfield Substantive Motion 2:**⁸ For judgment based on Jerussi's alleged
6 failure to comply with 35 U.S.C. § 135(b).

7 **Hadfield Substantive Motion 3:**⁹ For judgment based on an alleged failure
8 of Jerussi claims 60-63 of application 12/011,083 to comply with the written
9 description requirement of 35 U.S.C. § 112.

10 **Hadfield Substantive Motion 4:**¹⁰ To deny benefit to Jerussi of Jerussi
11 application 09/527,442 (filed 17 Mar. 2000) and application no. 10/720,134 (filed
12 25 Nov. 2003).

⁷ Corresponding to authorized (1) Hadfield 105,671 Substantive Motion 1,
(2) Hadfield 105,685 Substantive Motion 1 and (3) Hadfield 105,689 Substantive
Motion 1.

⁸ Corresponding to authorized (1) Hadfield 105,671 Substantive Motion 2,
(2) Hadfield 105,685 Substantive Motion 4 and (3) Hadfield 105,689 Substantive
Motion 4.

⁹ Corresponding to authorized Hadfield 105,671 Substantive Motion 4A.

¹⁰ Corresponding to authorized (1) Hadfield 105,685 Substantive Motion 2 and
(2) Hadfield 105,689 Substantive Motion 2.

1 **Hadfield Substantive Motion 5:**¹¹ Seeking judgment on the ground that
2 claims in the following Jerussi applications are not patentable based on an alleged
3 failure to comply with the written description requirement (35 U.S.C. § 112, first
4 paragraph):

- 5 (1) 10/720,134 and
6 (2) 11/091,518.

7 **H. Times for taking action**

8 The times for taking action are set out in the Appendix to the ORDER
9 AUTHORIZING MOTIONS and SETTING TIMES.

10 **I. Pages limits for some motions, oppositions and replies**

11 Notwithstanding (1) ¶¶ 121.2, 122.2.1 and 122.2.2 of the STANDING
12 ORDER (Paper 2) and (2) ¶¶ 1-3 of the MODIFICATION OF PROCEDURE
13 (Paper 3), the page limits for motions which correspond to two or more authorized
14 motions is increased to 30 pages for motions and oppositions and 12 pages for
15 replies.

¹¹ Corresponding to authorized (1) Hadfield 105,685 Substantive Motion 3 and
(2) Hadfield 105,689 Substantive Motion 3.

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